

REMARKS

This paper responds to the Office Action mailed November 2, 2004. In that Office Action, the Examiner rejected claims 28, 46 and 61 under 35 U.S.C. 102(b) as anticipated Odland and claims 29-45, 47-60 and 62-75 under 35 U.S.C. 103(a) as unpatentable over Odland in view of Wagner.

Procedural matter

In view of the rejections in the Action of November 2, 2004, applicants assume that the Examiner noted the response (of May 26, 2004) to a restriction requirement (mailed May 17, 2004), and withdrew the election requirement. Clarification is requested.

Rejection under 35 U.S.C. § 102

Claims 28, 46 and 61 were rejected under 35 U.S.C. § 102(e) as being anticipated by Odland. This rejection is respectfully traversed.

The Examiner referred to Figure 3 of Odland, explaining that, in Figure 3, the Odland patent discloses: “a probe comprising a proximal probe opening providing access to a supply line and a drainage line; a distal probe tip for introducing the probe into subcutaneous tissue, a supply line for introducing dripfeed solution into the probe, a drainage line; a dialysis section being formed between the supply line and the drainage line; the drip-feed solution flowing through the supply line in a flow direction, the flow direction being reversed in the area of the dialysis section and between the supply line and the drainage line.”

The applicants respectfully disagree with the Examiner’s interpretation with Figure 3 of Odland. Figure 3 of Odland shows a preferred pump configuration for use with the microcatheter of Figure 1 of Odland. *Odland, Column 15, lines 1-2*. The pump configuration does not include, among other things, a distal probe tip, a drainage line, a supply line, a dialysis section, etc. The pump configuration is merely a pump :

It can be seen that pump (14) includes both a substantially rigid external bulb (24) and an elastomeric internal bulb (26) containing fluid (28) to be delivered to the tissue ... A hypertonic solution (30) is positioned in the cavity between external bulb (24) and

internal bulb (26), which is retained in position, in part, by a semipermeable barrier (32) positioned between the hypertonic solution (30) and the recovery lumen (18). Optionally, and preferably, a fluid resistor (34) can be positioned between the fluid reservoir and the delivery lumen (16) in order to control flow. *Odland, Column 15, lines 2-14.*

Figure 1 illustrates a microcatheter used with the pump:

FIG. 1 shows an apparatus (10) having both a microcatheter component (12) and a delivery pump reservoir (14). The cross sectional and magnified views shown in FIGS. 1A and 2, respectively, show that delivery lumen (16) and recovery lumen (18) are separated by impermeable barrier (20) and surrounded by semipermeable membrane (22). *Odland, Column 14, lines 25-35.*

The microcatheter operates to move biological stimulating factors from one area of a site to another area of a site:

Once in place, the surfaces of microcatheter (12) serve a variety of roles, as determined by their location within the tissue (e.g., bone) and along the flow path of delivered fluid. In order, these roles include: a surface (22a) that serves to accumulate and remove biological stimulating factors (identified by o's) from the region of injured bone and transport them to surface 22(b), whereupon the factors are released into healthy bone, where they serve to stimulate the natural production of healing factors (identified by Δ's). The healing factors, in turn, are then accumulated and removed by portion (22c) and carried back into the region of injured bone, where they are themselves able to diffuse out from portion (22d) of the microcatheter surface. *Odland, Column 14, lines 42-55.*

Odland does not teach or suggest a drip-feed solution or a supply line for introducing a drip-feed solution. Further, Odland does not teach or suggest a micro-dialysis probe comprising dialysis section formed between a supply line and a drainage line nor a flow inversion in the area of the dialysis section between the supply line and the drainage line. Neither the microcatheter of Figure 1 of Odland nor the pump of Figure 3 of Odland discloses or suggests:

- a supply line for introducing drip-feed solution into the probe, the supply line having a dialysis opening in the vicinity of the probe tip;
- a drainage line formed as a hollow fiber, the hollow fiber being exposed to surrounding tissue in the vicinity of the probe tip;
- a dialysis section being formed between the supply line and the drainage line in the area of the supply line dialysis opening and the exposure of the hollow fiber to surrounding tissue;
- the drip-feed solution flowing through the supply line experiencing an inversion in the area of the dialysis section and between the supply line and the drainage line,

as recited in claim 28.

Similarly, Odland fails to disclose or suggest:

a supply line for introducing drip-feed solution into the probe,
a drainage line;
a dialysis section being formed between the supply line and the drainage line;
the drip-feed solution flowing through the supply line in a flow direction, the flow
direction being reversed in the area of the dialysis section and between the supply line
and the drainage line.

as recited in claim 61.

Nor does Odland disclose or suggest:

a supporting profile inserted into the hollow fiber, the supporting profile separating the
supply line from the drainage line, the supporting profile at least one overflow opening,
the drip-feed liquid flowing from the supply line into the drainage line in the area of the
overflow opening, the drip-feed liquid there experiencing an inversion,

as recited in claim 46.

For at least the preceding reasons, Odland does not anticipate claims 28, 46 and 61.
Reconsideration and withdrawal of the rejections under §102 are requested.

Rejection under 35 U.S.C. § 103

Claims 29-45, 47-60 and 62-75 were rejected under 35 U.S.C. § 103(a) as being
unpatentable over Odland in view of Wagner. This rejection is respectfully traversed.

In explaining the rejection, the Examiner states only: "The examiner of record would like
to point out that using the term 'star' to describe the profiles of the probe is considered a vague
description of the structural characteristic of the probe lumens. Recognizing that there are no
identical stars in the universe, it would not be unreasonable to contend that unless there is an
express structural description of the star shapes in the claims, the teachings of the cited patents
would be enough motivation to consider the disclosed profiles conventional in the art of probes."

It is thus unclear why the Examiner is citing Wagner. The applicants assume that the Examiner relies on Wagner to teach each of the limitations of claims 29-45, 47-60 and 62-75, and that the Examiner asserts that these teachings would have been obvious to add to the invention of Odland, asserted by the Examiner as teaching the limitations of claims 28, 46 and 61. For at least the reasons given above, Odland does not teach or suggest the limitations of claims 28, 46 and 61. Wagner teaches a drainage device for removing fluids by suction from body cavities. Wagner does nothing to correct the fundamental deficiencies in using Odland as a reference for rejecting claims 28, 46 and 61.

The applicants thus respectfully submit that claims 29-45, 47-60 and 62-75 are patentable over the combination of Odland and Wagner. Reconsideration is requested.

Conclusion

No fees have been generated by this paper, however, a petition to extend the time to respond is being submitted herewith, along with the appropriate fee. The Commissioner is hereby authorized to charge any deficiencies and credit any overpayments associated with the petition or this paper to Deposit Account No. 04-1420.

This application is in allowable form, and reconsideration and allowance are respectfully requested.

Respectfully submitted,

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Date:

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